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10/759,576	01/16/2004	Jian-Bing Fan	067234-0104	8734

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EXAMINER	
FORMAN, BETTY J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,576	FAN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8-10,14,16,18,20-22,25-28,31,33,37 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,8-10,14,16,18,20-22,25-28,31,33,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 28 April 2008 in which claims 1, 6, 14, 16, 18, 28, 37 and 38 were amended and claims 5, 7, 15, 17, 19, 32 and 34 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 17 January 2008 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 103(a) are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 1, 4, 6, 8-10, 14, 16, 18, 20-22, 25-28, 31, 33, 37 and 38 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4, 6, 8-10, 14, 16, 18, 20-22, 25-28, 31, 33, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No.

6,327,410, filed 11 Sept 1998) in view of Drmanac et al (EP 0392546, published 17 October 1990).

Regarding Claim 1, Walt et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres comprising a first and second microsphere, each microsphere comprising a plurality of target analytes covalently attached (i.e. bioactive agents, column 11, lines 41-45, 57-67) wherein the first and second microsphere have analytes from a different target source (e.g. rabbit, goat, mouse, Column 27, lines 30-60) wherein the microspheres are each encoded with an identifier to identify the analyte (Fig. 3 and Column 27, lines 30-60) and wherein the microspheres are randomly distributed on the surface (Column 4, lines 35-50).

Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (Column 11, lines 25-35)

Walt et al further teaches preferred target analytes are genomic DNA (Column 10, lines 38-42) and teaches the preferred embodiment wherein each microsphere has a single type of analyte (Column 11, lines 41-43). This, by definition, encompasses a teaching of microspheres having more than one type of analyte, but Walt does not specifically exemplify first and second microspheres, each having a plurality of different analytes. However, Drmanac teaches a similar composition comprising a first and second microsphere (discrete particle, (DP)), each comprising amplification product from fragmented genomic DNA, thus teaching different analytes on each DP (column 12 and column 13, lines 14-19) and labeled with an identifier binding ligands (Column 13, line 23-60).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microspheres of Walt et al by attaching the genomic fragments encoded by identifier oligos as taught by Drmanac. One of ordinary skill in the art would have been motivated to do so for the expected benefit of low cost and high throughput sequence determination as taught by Drmanac (Abstract and Column 1, lines 26-32). It would have been further obvious to one of ordinary skill to encode the microspheres of Walt with the identifier binding ligands of Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Regarding Claim 4, Walt et al teach the microspheres are encoded (Fig. 3 and Column 27, lines 30-60) but do not teach nucleic acid identifier binding ligands. However, Drmanac teaches the similar array wherein the particle is encoded using oligonucleotides wherein the analyte is identified by hybridization to the oligos (Column 7-8).

It would have been obvious to one of ordinary skill to encode the microspheres of Walt with the nucleic acid identifier binding ligands as taught by Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Regarding Claim 6, Walt et al disclose the array wherein the nucleic acids are genomic DNA (Column 11, lines 25-35) and Drmanac teach the target analytes are genomic DNA (Abstract).

Regarding Claim 8, Walt et al disclose the array wherein the substrate is a fiber optic (Column 5, lines 24-31).

Regarding Claim 9, Walt et al disclose the array wherein the substrate is plastic (Column 5, lines 37-40).

Regarding Claim 10, Walt et al disclose the array wherein the discrete sites are wells (Column 5, lines 61-67).

Regarding Claim 14, Walt et al disclose an array composition comprising a substrate having discrete sites and a population of microspheres comprising a first and second microsphere, each microsphere comprising a plurality of target analytes covalently attached (i.e. bioactive agents, column 11, lines 41-45, 57-67) wherein the first and second microsphere have analytes from a different target source (e.g. rabbit, goat, mouse, Column 27, lines 30-60) wherein the microspheres are each encoded with an identifier to identify the analyte (Fig. 3 and Column 27, lines 30-60) and wherein the discrete sites have a density of 10,000 to 100,000,000 per cm^2 (Column 5, lines 4-31).

Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (Column 11, lines 25-35).

Walt et al further teaches preferred target analytes are genomic DNA (Column 10, lines 38-42) and teaches the preferred embodiment wherein each microsphere has a single type of analyte (Column 11, lines 41-43). This, by definition, encompasses a teaching of microspheres having more than one type of analyte, but Walt does not specifically exemplify first and second microspheres, each having a plurality of different analytes. However, Drmanac teaches a similar composition comprising a first and second microsphere (discrete particle, (DP)), each comprising amplification product

from fragmented genomic DNA, thus teaching different analytes on each DP (column 12 and column 13, lines 14-19) and labeled with an identifier binding ligands (Column 13, line 23-60).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microspheres of Walt et al by attaching the genomic fragments encoded by identifier oligos as taught by Drmanac. One of ordinary skill in the art would have been motivated to do so for the expected benefit of low cost and high throughput sequence determination as taught by Drmanac (Abstract and Column 1, lines 26-32). It would have been further obvious to one of ordinary skill to encode the microspheres of Walt with the identifier binding ligands of Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Regarding Claim 16, Walt et al disclose the composition wherein a plurality of different analytes are covalently attached to microspheres and the microspheres are distributed in the discrete sites i.e. the analytes are covalently attached to the microspheres which randomly distributed and covalently attached to the substrate (Column 4, lines 42-55; Column 6, lines 48-50; and Column 11, lines 63-65).

Regarding Claim 18, Walt et al disclose the array wherein the nucleic acids are genomic DNA (Column 11, lines 25-35) and Drmanac teach the target analytes are genomic DNA (Abstract).

Regarding Claim 20, Walt et al disclose the array wherein the substrate is a fiber optic (Column 5, lines 24-31).

Regarding Claim 21, Walt et al disclose the array wherein the substrate is plastic (Column 5, lines 37-40).

Regarding Claim 22, Walt et al disclose the array wherein the discrete sites are wells (Column 5, lines 61-67).

Regarding Claim 25, Walt et al disclose the composition wherein the discrete sites are at a density of about 100,000 to 10,000,000 per cm^2 (Column 5, lines 4-31).

Regarding Claim 26, Walt et al disclose the composition wherein the discrete sites are at a density of about 10,000,000 to 1,000,000,000 per cm^2 (Column 5, lines 5-31).

Regarding Claim 27, Walt et al disclose the composition wherein the discrete sites are at a density of about 10,000 to 100,000 per cm^2 (Column 5, lines 4-31).

Regarding Claim 28, Walt et al disclose an array composition comprising a population of microspheres comprising a first and second microsphere, each microsphere comprising a plurality of target analytes covalently attached (i.e. bioactive agents, column 11, lines 41-45, 57-67) wherein the first and second microsphere have analytes from a different target source (e.g. rabbit, goat, mouse, Column 27, lines 30-60) wherein the microspheres are each encoded with an identifier to identify the analyte (Fig. 3 and Column 27, lines 30-60) and wherein the microspheres are randomly distributed on the surface (Column 4, lines 35-50).

Walt et al disclose the array wherein the analytes are nucleic acids i.e. probe and target hybridized to the target (Column 11, lines 25-35).

Walt et al further teaches preferred target analytes are genomic DNA (Column 10, lines 38-42) and teaches the preferred embodiment wherein each microsphere has a single type of analyte (Column 11, lines 41-43). This, by definition, encompasses a teaching of microspheres having more than one type of analyte, but Walt does not specifically exemplify first and second microspheres, each having a plurality of different analytes. However, Drmanac teaches a similar composition comprising a first and second microsphere (discrete particle, (DP)), each comprising amplification product from fragmented genomic DNA, thus teaching different analytes on each DP (column 12 and column 13, lines 14-19) and labeled with an identifier binding ligands (Column 13, line 23-60).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microspheres of Walt et al by attaching the genomic fragments encoded by identifier oligos as taught by Drmanac. One of ordinary skill in the art would have been motivated to do so for the expected benefit of low cost and high throughput sequence determination as taught by Drmanac (Abstract and Column 1, lines 26-32). It would have been further obvious to one of ordinary skill to encode the microspheres of Walt with the identifier binding ligands of Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Regarding Claim 31, Walt et al teach the microspheres are encoded (Fig. 3 and Column 27, lines 30-60) but do not teach nucleic acid identifier binding ligands. However, Drmanac teaches the similar array wherein the particle is encoded using

oligonucleotides wherein the analyte is identified by hybridization to the oligos (Column 7-8).

It would have been obvious to one of ordinary skill to encode the microspheres of Walt with the nucleic acid identifier binding ligands as taught by Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Regarding Claim 33, Walt et al disclose the array wherein the nucleic acids are genomic DNA (Column 11, lines 25-35) and Drmanac teach the target analytes are genomic DNA (Abstract).

Regarding Claim 37, Walt et al teach the preferred target analytes are genomic DNA (Column 10, lines 38-42) and teaches the preferred embodiment wherein each microsphere has a single type of analyte (Column 11, lines 41-43). This, by definition, encompasses a teaching of microspheres having more than one type of analyte, but Walt does not specifically exemplify first and second microspheres, each having a plurality of different analytes.

However, Drmanac teaches a similar composition comprising a first and second microsphere (discrete particle, (DP)), each comprising amplification product from fragmented genomic DNA, thus teaching different analytes on each DP (column 12 and column 13, lines 14-19) and labeled with an identifier binding ligands (Column 13, line 23-60).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microspheres of Walt et al by attaching the

genomic fragments encoded by identifier oligos as taught by Drmanac. One of ordinary skill in the art would have been motivated to do so for the expected benefit of low cost and high throughput sequence determination as taught by Drmanac (Abstract and Column 1, lines 26-32). It would have been further obvious to one of ordinary skill to encode the microspheres of Walt with the identifier binding ligands of Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Regarding Claim 38, Walt et al teach the composition of Claim 14 wherein the microspheres are each encoded with an identifier to identify the analyte (Fig. 3 and Column 27, lines 30-60) and wherein the microspheres are randomly distributed on the surface at discrete sites (Column 4, lines 35-50). Walt et al teach the microspheres are encoded (Fig. 3 and Column 27, lines 30-60) but do not teach nucleic acid identifier binding ligands. However, Drmanac teaches the similar array wherein the particle is encoded using oligonucleotides wherein the analyte is identified by hybridization to the oligos (Column 7-8).

It would have been obvious to one of ordinary skill to encode the microspheres of Walt with the nucleic acid identifier binding ligands as taught by Drmanac for the expected benefit of fast and frugal data generation (Column 4, lines 33-38).

Response to Arguments

4. Applicant asserts that neither Walt or Drmanac teach microspheres with a plurality of different target nucleic acids covalently attached to each individual microsphere as claimed.

The argument has been considered but is not found persuasive. Drmanac teaches preparation of the discrete particles (DP) includes a library of genomic clones in a microtiter plate, adding DP to each well and coupling the DNA to the DP (Column 7, lines 22-27). Drmanac further teaches the DP/genomic fragments are prepared in parallel using genomic fragments from multiple individuals (Column 12, lines 18-27). Drmanac further teaches the method of attaching the genomic fragments to the DP via covalent linkage via hybridization and ligation of single-stranded ends (Column 13, lines 30-40). Hence, the DP of Drmanac contain double-stranded genomic fragments, each strand of the fragment provides one of target molecules thereby providing each DP with two (i.e. a plurality) different target molecules. Furthermore, Drmanac specifically teaches the DP having two targets and detection using two complementary probes (Column 18, lines 45-58).

For the above reasons, the arguments are not found persuasive. The rejections are maintained and made final.

Conclusion

5. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
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